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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDISIM, LTD Plaintiff - Counterdefendant v. BESTMED, LLC Defendant - Counterclaimant	Civil Action No.: 10-cv-2463 (SAS) (RLE)

BESTMED, LLC'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO STRIKE PORTIONS OF PLAINTIFF'S EXPERTS, LIPSON AND KEEGAN

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I. Introduction

District courts are the gatekeepers of expert evidence. *Kumho Tire. Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993). It is up to the courts to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. As the gatekeeper, this Court should strike various portions of Medisim's experts' reports as being contrary to this Court's claim construction Order; irrelevant; and failing to pass muster under the requirements of Rule 702 and *Daubert* for reliability. Moreover, the probative value of many of the opinions is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.

II. Relevant Law

Rule 702 provides: "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed.R.Evid. 702. The proponent of expert evidence must establish admissibility under by a preponderance of the proof. *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987); see also *Velez v. Sony Discos*, No. 05 Civ. 0615, 2007 WL 120686, at *4 (S.D.N.Y. Jan. 16, 2007).

The Supreme Court set out a non-exclusive list of factors for courts to use in assessing the reliability of scientific expert testimony. These include: (1) whether the expert's technique or theory can be or has been tested that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to

peer review and publication; (3) the known or potential rate of error of the technique or theory when applied and the existence and maintenance of standards and controls that govern the application of the expert's process; and (4) whether the technique or theory has been generally accepted in the relevant community of experts. *Daubert*, 509 U.S. at 590 n.9, 592-94.

Rule 403 further provides that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed.R.Evid. 403. For example, an expert may not usurp the role of the court in instructing on the law. *United States v. Lumpkin*, 192 F.3d 280, 289 (2d Cir.1999).

III. Portions Of Medisim's Technical Expert's Report Should Be Stricken As Contrary to This Court's Claim Construction Order And For Lack of Reliability

Dr. Lipson, Medisim's technical expert, offers numerous opinions that should be stricken. Lipson simply disregards the Court's claim construction Order. Doc. 45. As a result of his clear disregard, as well as his failure to adhere to acceptable scientific principles, Lipson's opinions are unreliable. In some cases, Lipson's testimony requires no specialized training or knowledge, even if he possessed the requisite expertise, which he does not.

A. Lipson's Opinions Related To Whether The Accused Products Meet The "Deep Tissue Temperature" Limitation Should be Stricken

The '668 Patent claims require "a processing unit configured ... to calculate, a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors." Doc. 45 at 5-6. Lipson opines on whether the Accused Products meet the limitation, and also whether Medisim's admitted pre-critical date sales of its FHT-1 constitute an "on-sale bar" based on his definition of "deep tissue temperature." Lipson chooses, however, to disregard the agreed meaning for "deep tissue temperature" that was incorporated in this Court's claim construction Order. Moreover, Lipson relies on junk science and unreliable testing methodology to fabricate his opinions. Thus, the entirety of Lipson's opinions regarding

the "deep tissue temperature" limitation should be stricken.

1. Lipson's Opinions Should Be Stricken Because He Disregards The Court's Order on "Deep Tissue Temperature"

The term "deep tissue temperature" is in all of the asserted claims. Medisim argued that this term meant "the steady state temperature at the measurement site," and explained that "steady state" was the temperature a thermometer would reach if left at the measurement site until it reached thermal equilibrium, i.e., the temperature stopped rising. See e.g., 4/28/11 Tr. at 104:3-7. BestMed opposed Medisim's proposed construction stating, *inter alia*:

> Mr. KUO: The problem with [Medisim's] definition ... is these additions of stable temperature, minimally affected, now this concept of steady state. It's just not in the claim.
>
> The COURT: No, it's not in the claim, I agree.

See 4/28/11 Tr. 105:16-21. After this discussion and additional discussions off the record, Medisim conceded its position and agreed that the definition for "deep tissue temperature" would not mean a steady state temperature. 4/28/11 Tr. at 108:17-109:20. Instead, Medisim agreed that "deep tissue temperature" was defined by the claim itself, namely, a body temperature "at a location under the skin that is a source of heat conducted to the one or more temperature sensors." Id., see also, Doc. 45 at 29-30; Ex. 2, col. 10:13-15.

Despite Medisim's voluntary withdrawal of its "steady state" argument, Lipson backtracks and argues that "deep tissue temperature is ... a steady state or stable temperature at the measurement site." Ex. 1 at 11. He then bases his opinions on whether the Accused Products meet the "deep tissue temperature" limitation on this construction the same one Medisim dropped. For example, he states that the Accused Products are "predictive devices" and that "with only one sensor measuring skin temperature for a device that is predictive means that the prediction must be of a steady state value at the measurement site." Id. at 27; see also, pages 28-30. Lipson provides no factual support for the latter. All of Lipson's opinions regarding whether

the Accused Products meet the "deep tissue temperature" limitation based on his "steady-state" claim construction should be stricken: (1) as contrary to the Court's claim construction Order; (2) as completely at odds with Medisim's representations at the claim construction hearing (4/28/11 Tr. at 108:17-109:20); and (3) because his factual basis for his opinions is nonexistent.

Similarly, Lipson bases his rebuttal opinions regarding whether Medisim's pre-critical date sales of its FHT-1 thermometer meet the "deep tissue temperature" limitation on his "steady state" claim construction. See Ex. 3 at 20-26. By basing his opinions on a wrong claim construction, a claim construction that is contrary to the claim construction Medisim had agreed to in court, Lipson's opinions are necessarily unreliable and impermissibly confusing to the fact finder. Indeed, any testimony based on Lipson's inconsistent claim construction would necessarily involve his testifying that "deep tissue temperature" is a "steady state temperature." This would be an improper invasion of the Court's duties to instruct on the meaning of the claims. *Lumpkin*, 192 F.3d at 289; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71, (Fed.Cir.1995) (en banc), aff'd, 517 U.S. 370 (1996). Accordingly, all of Lipson's opinions related to whether the pre-critical date sales of Medisim's FHT-1 device meet the "deep tissue temperature" limitation based on his "steady-state" claim construction should also be stricken.

2. Lipson's Rehashed Claim Construction Argument Should Also be Stricken as Being Clearly Baseless

Notwithstanding a clear disregard for this Court's claim construction Order and employing his own definition for "deep tissue temperature," Lipson's definition for "deep tissue temperature" is simply nonsensical. The '668 Patent claims define "deep tissue" as a location *"under the skin*." By contrast, the measurement site is the external surface of the body, i.e., the skin's surface, not a location under the skin. Doc. 45 at 36. Moreover, the entire concept of surface temperature at steady state is "not even in the claim." See 4/28/11 Tr. 105:16-21. In fact, the words "steady state" appear nowhere in the '668 Patent. Ex. 2.

Indeed, the difference between a surface temperature, even at "steady state," and the temperature of the source of the heat under the skin is exemplified by Medisim's own demonstrative materials depicting a hot water pipe, with insulation, and a cover. Ex. 4. Medisim describes these parts as analogous to a person's blood vessels, tissue layers, and skin, respectively. It is common sense that a thermometer measuring the surface temperature of the pipe cover would never reach the temperature of the hot water in the pipe no matter how long it was left there. That is the purpose of the insulation, and likewise the tissue layers in a person's body. Lipson's notion that "deep tissue temperature" is the skin temperature at thermal equilibrium is contrary to the laws of physics and clearly wrong.

The '668 Patent itself makes it clear that the temperature at the measurement site, i.e., the surface temperature, is different from deep tissue temperature. The '668 Patent explains that local temperature (used synonymously with deep tissue temperature):

> is less affected than the surface temperature at the measurement site is to external factors such as ambient temperature and humidity. The local temperature is also less subject to variations in the body's heat regulation at the body's extremities. Consequently, there is a closer correlation between local temperature and core body temperature than there is between surface temperature and core body temperature. Ex. 2, col. 7:1-8.

Deep tissue temperature is thus defined as being different from one's skin surface temperature. Medisim even differentiated skin temperature from deep tissue temperature during prosecution of the '668 Patent: "deep tissue itself is also clearly distinguished from the skin temperature [Ex. 2, col. 1:58-col. 2:5] ... [it] is the temperature of the body at a location under the skin that is the source of heat conducted to one or more temperature sensors on the body surface." Ex. 5.

Lipson even contradicts his claim construction by admitting that "[s]kin temperature is determined by the balance of heat provided by subcutaneous tissues and heat loss to the environment." Ex. 1 at 10-11. Tissues under the skin, i.e., subcutaneous tissues, experience heat loss such that the skin surface temperature, even at equilibrium, is different from body

temperature under the skin. Lipson's claim construction arguments are frivolous. He should be prevented from offering any such testimony, or any opinions based on such a claim construction.

3. Lipson's Tests Are "Junk Science," Not Real Science

A purpose of the *Daubert* inquiry is "[t]o make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. Lipson's test fall woefully short of meeting this requirement.

The determination of whether an Accused Product meets the "deep tissue temperature" limitation under the actual claim construction requires Medisim to prove that the Accused Product calculates a body temperature at a location "under the skin." Lipson's handful of human tests are limited to measurements taken at the skin's surface. Ex. 1 at 24. As such, Lipson's tests fail *ab initio* to demonstrate a temperature "under the skin" as required by the claim.

Lipson also fails to even compare temperatures of a person's body under the skin with measurements taken at the skin's surface to justify his conclusion that the supposed steady state temperature is representative of a person's body temperature under the skin. Instead, Lipson simply concludes without any testable basis or other evidentiary support that a person's skin temperature at equilibrium is an accurate representation of his or her temperature under the skin. Lipson's rank conclusion does not pass muster under Rule 702. *Daubert*, 509 U.S. at 592-94.

Lipson's supposed empirical tests are also based on a faulty premise. He measures temperatures of a water bath and simply assumes that water bath temperatures simulate deep tissue temperature. Id. at 24. No rationale is given for how or why a water bath temperature is at all related to a deep tissue temperature. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Thus, Lipson's water bath analysis collapses.

Lipson's opinions should also be excluded because he fails to consider critical facts. The claims require a configured processing unit. A processing unit's operation is dictated by its programming. *See WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339 1348-49 (Fed.Cir. 1999). Whether the Accused Product's microprocessor performs the recited functions, depends on the source code for the device, and in particular, the portions of the source code that, when compiled, controls the operation of the device. Goldberg Decl. at ¶12-15.

Lipson, however, neglects to cite to a single specific portion of the source code for the Accused Products to support his opinions. Lipson mentions only in passing that he reviewed the source code (Ex. 1 at 18-19), yet he represents that he did not rely on the code in formulating his opinions, as is demonstrated by his omission of the source code from his "List of Documents Relied Upon." Id. at Exhibit B. This failure to consider the critical factor that controls the operation of the thermometer further renders his opinions unreliable. *Nimely v. City of New York*, 414 F.3d 381, 396 97 (2d Cir.2005) ("when an expert opinion is based on data, methodology, or studies that are simply inadequate to support conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony" (internal quotations omitted)), *see also, In re Omeprazole Patent Litigation*, 490 F.Supp.2d 381, 401 (S.D.N.Y. 2007). For these reasons as well, all of Lipson's opinions based on his own unsupportable definition for "deep tissue temperature" should be excluded.

B. Lipson's Opinions Related To Whether The Accused Products Meet The "Core Body Temperature" Limitation Should be Stricken

Despite this Court's unequivocal claim construction to the contrary, Lipson opines that "peripheral temperatures" such as oral or rectal, constitute an estimation of core body temperature, and thus a thermometer that displays an oral equivalent temperature meets the "core body temperature" limitation. It is hard to see how the Court could have been any clearer in

stating that "peripheral temperatures," such as oral and rectal temperatures, are not a "core body temperature." Lipson's revamped "core body temperature" argument is contrary to the Court's claim construction Order and should be stricken.

Moreover, Lipson's tests are clearly unreliable in that he fails to adhere to acceptable scientific methods, misuses test equipment, and fails to measure the correct body temperatures. For these reasons as well, his opinions on "core body temperature" should be stricken.

1. Lipson Improperly Attempts to Repackage Medisim's Rejected "Core Body Temperature" Arguments

Medisim already argued a definition for "core body temperature" that could include peripheral body temperatures such as oral, rectal or axillary temperatures. Doc. 45 at 32-33. The Court flatly rejected Medisim's arguments, and made it clear that calculating a peripheral body temperature cannot be a calculation of "core body temperature." "The patent distinguishes 'core body temperature' and peripheral temperatures based on ... how indicative they are of the subject's health." Doc. 45 at 33. "[T]he plain language of the '668 Patent treats core body temperature and peripheral temperature as distinct terms." Id. To include peripheral temperatures, such as an oral temperature, in the definition of core body temperature "does not account for these distinctions and conflates the two temperatures. Id. at 33-34. "It would defy common sense to ... define 'core body temperature' to include peripheral temperatures ...." Id. at 34, n.127.

Yet, Lipson devotes several pages of his report to his arguments for why oral temperature readings are supposedly understood in the art to be an acceptable approximation of core body temperature. For example, Lipson states: "literature in the field indicates that oral temperature is a clinically acceptable approximation of the core body temperature" Ex. 1 at 7-8, 30. He further states that "if the device is displaying an 'oral temperature,' then it is necessarily calculating a core temperature as the Court has defined the terms of the patent." Ex. 1 at 31. Even if there are examples in the field for differing usages of "core body temperature," this is irrelevant here.

"Core body temperature" is defined as the temperature of blood in the pulmonary artery." Doc. 45 at 34. Lipson's blatant disregard is a knowing violation of this Court's construction for "core body temperature" and warrants exclusion.

The '668 Patent itself highlights the absurdity of Lipson's side-step of the Court's claim construction. Peripheral temperatures, such as oral, have a poor correlation to core body temperature. Ex. 1, col. 1:39-40 ("there is a poor correlation between ... peripheral temperatures with the core body temperature."). "The purpose of the invention is to determine a person's core body temperature in a non-invasive but more accurate manner." Doc. 45 at 34 n.127. Lipson's attempt to expand the scope of "core body temperatures" to include the computation of a peripheral temperature by way of the definition for "calculate" would effectively erase the '668 Patent's distinction of the different categories of body temperatures. See, 4/28/11 Tr. at 129-130. In other words, if the calculation of any body temperature constitutes an approximation of the temperature of blood in a person's pulmonary artery, then the '668 Patent claims have no meaning. This is clearly not what was intended by the Court's claim construction.

Moreover, contrary to Medisim's counsel's representations (10/6/11 Tr. at 19-20), Lipson's and Medisim's arguments are nothing but a transparent attempt to back door peripheral temperatures into the scope of the '668 Patent by way of the claim term "calculating." Lipson's repackaging of Medisim's rejected claim construction argument would incorrectly render the '668 Patent's distinction between peripheral temperatures and core body temperature meaningless.

Lipson's retread of Medisim's "core body temperature" arguments simply makes no logical sense. The '668 Patent states there is close correlation between deep tissue temperature and core body temperature, and by contrast, there is a "poor correlation between external and peripheral temperatures with the core body temperature." Ex. 1, col. 7:6-8; col. 1:39-40. It defies logic for one to determine deep tissue temperature, and then correct it for a peripheral

temperature, such as oral temperature, since the '668 Patent states that deep tissue temperature would have a more accurate correlation to core temperature than peripheral temperatures. Lipson's re-construction would defeat the very purpose of the supposed invention, namely, "to determine a person's core body temperature in a non-invasive but more accurate manner.[1] Doc. 45 at 34, n.127. Accordingly, Lipson's opinions should be excluded.

2. Lipson's "Core Body" Opinions Are Unreliable

Lipson's opinions regarding "core body temperature" should also be stricken because he fails to consider critical evidence. *See Brooks v. Outboard Marine Corp.*, 234 F.3d 89, 91 92 (2d Cir.2000) ("[F]ailure to test theory can justify a trial court's exclusion of the expert's testimony."). "Core body temperature" is defined as "the temperature of blood in the pulmonary artery." Id at 32-34. Techniques for measuring the temperature of a person's blood in the pulmonary artery are well known, and even described in the article "Core Body Temperature Measurement: a Comparison of Axilla, Tympanic, Membrane and Pulmonary Artery Blood Temperature," Fulbrook, *Intensive Care Nursing*, Oct. 1997, 13(5):266-72, which is incorporated by reference in the '668 Patent. Ex. 6. Despite this, Lipson chose not to conduct any tests of subjects comparing temperatures measured with the Accused Product with temperature measurements of persons' blood in his or her pulmonary artery.

Instead, Lipson relies on smoke and mirrors. Lipson measured his oral temperature with a KD-192 oral thermometer and his temperature measured with the Accused Product, and concluded that his oral measurement was essentially the same as the temperature he obtained with the Accused Product. Ex. 1 at 19-20. As discussed, this oral reading cannot be the claimed core body temperature.

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[1] BestMed's expert states "within the context of the '668 Patent that oral temperatures would not be considered an acceptable approximation or estimation of core body temperature". Goldberg Decl. ¶ 21-24.

Even if Lipson's reliance on an oral thermometer reading to determine the temperature of blood in the pulmonary artery was appropriate, he utterly fails to adhere to the fundamental standards for testing medical devices. Lipson obtains only a single measurement taken according to the instructions for the oral thermometer and compares it to a single measurement taken with the Accused Product. Single measurements do not constitute a legitimate sample size. Where there is variability amongst test subjects, multiple measurements are necessary.[2] See e.g., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071072.htm (section 4.7); see also Goldberg Decl. ¶ 5-10.

Beyond his improper reliance on a single-sample "study," Lipson then incredibly proceeds to purposefully misuse the test equipment. Ex. 1 at 19-20. Lipson took a temperature measurement with the KD-192 oral thermometer immediately after drinking hot tea or after drinking cold water in hopes of establishing that the Accused Product's measurement was not of his oral temperature. Id. The KD-192 instructions expressly state, however, "[d]o not take any temperature measurement after eating or drinking, exercising, talking, smoking and showering or bathing for at least 15 minutes." Ex. 7. Lipson even knew that his procedure would give a false reading, as highlighted by his admission that oral temperature measurements are influenced by drinking hot or cold beverages. Ex. 1 at 20. This reliance on a procedure Lipson knew to be a misuse of the KD-192 demonstrates the abject unreliability of his opinions.

Lipson's concocted "core temperature accuracy test" also fails under *Daubert*. Id. at 22. In his test, Lipson first takes temperatures with the Accused Product of a water bath while in a "test mode." In this test mode the Accused Product will provide a direct temperature measurement of the actual water bath temperature (similar to a reading one would obtain using a mercury

[2] Lipson admits that results will vary "depending on the individual and on the individual's ambient temperature." Id. at 20.

thermometer), as opposed to a calculated temperature measurement. As stated above, Lipson fails to give any rationale for the assumption that the water bath measurement is representative of a deep tissue temperature. Lipson's test is entitled to no consideration. *See General Electric*, 522 U.S. 136 at 146. Moreover, according to the claims, deep tissue temperature is a calculated value, i.e., it is not an actual temperature measurement. Ex. 2, col. 10:13-15. Thus, whether the Accused Product can measure temperature directly is irrelevant. His conclusions founded on his incorrect presumption are unwarranted, not dependable, and should be excluded.

In addition to the errors in Lipson's "core temperature accuracy test" methodology, common sense also demonstrates that his conclusions lack any reliability. Lipson states that the display temperature for the Accused Products is always higher than the test mode reading, and therefore, the difference must be a correction for "core body temperature." A readily apparent flaw in Lipson's reasoning is his assumption that any correction must be the claimed correction from deep tissue temperature is to "a core body temperature." Even if there is a correction, that does not mean that the correction is for the "temperature of blood in the pulmonary artery." It could be for some other body temperature. The '668 Patent itself proves Lipson's assumption to be false by way of the incorporated by reference teachings of Pompei '685 Patent, which explains that adjustments for any number of different body temperatures, such as core, oral or rectal, can be made. Ex. 8, col. 4:9-17. Compounding the errors in Lipson's reasoning is his specious assumption that an oral temperature reading is a proper estimate of a core body temperature, which led to his failure to compare any measurements of a person's pulmonary artery blood temperature with the Accused Product's display temperature.

Lipson's water bath testing methodology also lacks any scientific or even logical reliability. Lipson takes temperatures of a water bath with the Accused Products in the "normal mode." Ex. 1 at 22-23. He also takes temperature readings of the same water bath with the

Accused Products in "test mode." Id. Lipson then compares the results and reasons that since "normal mode" readings are higher than "test mode" readings, that the Accused Product's algorithm includes calculation of one temperature followed by correction for another. Id. Lipson's analysis assumes that the "test mode" measurement is corrected to the "normal mode." This is wrong. If Lipson had bothered to study the computer code for the Accused Products, assuming *arguendo* that he is even able to do so, he would have determined that the section of the code controlling the "test mode" is different from the code controlling the "normal mode." Goldberg Decl. at ¶18-20. This defect in Lipson's experiments should have been readily apparent given that readings in the "test mode" require equilibration of the thermometer, which take several minutes, whereas a reading in "normal mode" requires but a few seconds. As such, the "test mode" reading cannot be the first step in obtaining the display temperature in "normal mode." Lipson's failure to analyze the source code led to his failure to recognize the non sequitur in his analysis and further epitomizes the lack of reliability in Lipson's opinions based on his "junk science."

Lipson's decision to ignore the source code for the Accused Product also renders his opinions unreliable. *See Nimely*, 414 F.3d at 396-97. The '668 Patent claims require first calculating "deep tissue temperature," and then calculating "core body temperature" by correcting the calculated "deep tissue temperature" value. Whether the actual Accused Product performs this two-step calculation requires analysis of the source code, yet Lipson skips this step. Indeed, Lipson fails to point to any algorithm in the source code of the Accused Product performing this two-step calculation.

C. Lipson's Opinions Regarding 510(k) Submissions Require No Expert Testimony And Are Of No Assistance To The Factfinder

Rule 702 limits expert testimony to "scientific, technical, or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue...." Fed.R.Evid. 702. A 510(k) is a submission made to FDA to demonstrate that the device to be

marketed is at least as safe and effective as a legally marketed device. 21 CFR 807.92(a)(3).

Lipson opines about what a 510(k) submission is, what the statements in various 510(k) submissions mean, and what is required for a 510(k) submission. Lipson's testimony on these issues should be precluded in that they require no specialized knowledge or skill. The contents of a 510(k) submission are available to the public and easily understood without need for a purported expert. See e.g., http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm. Moreover, Lipson's background demonstrates no specialized knowledge or skill on his part regarding 510(k) submissions, even if it were appropriate.

There is no specialized knowledge necessary to read a 510(k). Lipson merely cuts and pastes portions of K-Jump's 510(k)'s into his infringement chart, and then offers his opinions regarding the motivations behind them. Ex. 1 at 26-37. The contents of the 510(k) submissions are self-evident, and do not require a witness clothed in the guise of an expert to parrot what a factfinder can read for himself or herself. A factfinder is just as able to read K-Jump's 510(k) submissions as is Lipson, and determine for himself or herself what is stated. As such, Lipson's opinions are of no assistance to the trier of fact and should be excluded. Fed.R.Evid. 702.

Moreover, Lipson's stated qualifications fail to offer any indication that he possesses any special experience (even if it existed) to qualify him as an expert on 510(k) submissions. Lipson does not mention anywhere in his report or attachments thereto that he has even worked with 510(k) submissions. Lipson is simply incompetent to offer expert testimony on this issue.

D. Lipson's Enablement Opinions Should Be Excluded Because He Ignores The Relevant Law

In his rebuttal report Lipson opines on the supposed enablement of the '668 Patent claims. Ex. 3 at 17-19. His opinions should be excluded as being contrary to the law on enablement, as being based on his improper claim construction, and as being merely conclusory.

Enablement is determined as of the filing date of the patent's application. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed.Cir.1999). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed.Cir. 1997). "Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1, is a question of law ... based on underlying factual inquiries...." *See Enzo*, 188 F.3d at 1369. Various factors regarding "undue experimentation" include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 736-37 (Fed.Cir. 1988).

Lipson shirks these legal principles in espousing his conclusory opinions. Lipson neglects to cite any part of the '668 Patent specification for a teaching on how to make the claimed thermometer using only a single temperature sensor. Instead, Lipson relies on a reference cited during the prosecution of the '668 Patent (Weiss). Ex. 3 at 18. Lipson then links Weiss to a patent issued to Gregory, which formed no part of the prosecution for the '668 Patent, and summarily claims that "one of ordinary skill in the art would know to look at U.S. patents that reference Gregory." Id. Lipson then refers to a patent issued to Seifert, which has no connection to the '668 Patent prosecution for a supposed teaching of a single-sensor predictive thermometer. Id. The Seifert thermometer, however, is not the patented thermometer. In any event, Lipson's reliacne on what person's skill in the art might supposedly know is irrelevant. One may not rely on the knowledge of a person of ordinary skill in the art to supply features of the claimed invention. *Alza Corp. v. Andrx Pharm.*, 603 F.3d 935, 941 (Fed.Cir. 2010). Lipson's arguments and his

referenced patents are wholly irrelevant as a matter of law.

Enablement must also be determined based on the specification at the time of filing. *Enzo*, 188 F.3d 1371-72. Lipson's references were not part of the '668 Patent at any time, let alone at the time of filing. The references are not "incorporated by reference," and thus, they are not part of the '668 Patent specification. Cf. *Adv. Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed.Cir.2000) (Materials incorporated by reference in a patent are effectively part of the patent as though they were explicitly included in their entirety within the patent document). The Weiss patent did not even become part of the '668 Patent prosecution until June 29, 2007 (Ex. 9) over a year after filing. Worse yet, Gregory and Seifert are completely absent from the '668 Patent prosecution. As such, none of Lipson's cited patents relied upon for his enablement opinions are part of the '668 Patent specification, and can form no basis for his opinions.[3]

Other than his misplaced arguments regarding the various patents mentioned, Lipson offers only the unsupported claim:

> Or one can measure local deep tissue temperature by using a single sensor at the forehead measuring site until it reaches steady state temperature (approximately 10 minutes), and clinically measure oral temperature in order to obtain the values that can be used to calculate core body temperature and the difference between core body temperature and local deep tissue temperature. Ex. 3 at 18.

Lipson offer no testable support for his conclusion; instead, merely offering his proclamation, which is clearly improper. *See Daubert*, 509 U.S. at 592-94 (conclusory statements that cannot reasonably be assessed for reliability should be excluded). Lipson also relies on the incorrect definition of "deep tissue temperature," and again improperly conflates core temperature and peripheral temperature. For these reasons as well, the aforementioned opinions of Medisim's technical expert should be excluded.

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[3] In addition, Lipson utterly fails to apply any of the *Wands* factors to his analysis; further rendering his opinions improper.

IV. Medisim's "Survey" Expert Report Should Be Stricken

In addition to Medisim's technical expert, the opinions of Medisim's survey expert, Dr. Keegan, should also be excluded. BestMed requests that the Court exclude Keegan's opinions concerning the survey he conducted on behalf of Medisim, as well as the survey itself because of numerous methodological flaws. "[I]f the survey suffers from substantial methodological flaws, it will be excluded under both Rule 403 and Rule 702." *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 581 (S.D.N.Y. 2007).

Keegan's report describes a survey he designed purportedly showing that 83% of respondents believe both the "Medisim thermometer" and "BestMed thermometer"[4] are manufactured by the same company or by companies that are "affiliated, connected or associated" with one another. Ex. 3. Keegan's Survey suffers from several fatal flaws including: 1) fabrication of non-existent market conditions; 2) use of an artificially manufactured control sharing few similarities with the Test condition; 3) selection of a universe of respondents who are not potential purchasers of electronic thermometers; and 4) biasing the respondents with a suggestive statement. Given these serious flaws, the Keegan Survey fails to meet the standards set by the Rules 702 and 403 and should be excluded.[5]

A. The Keegan Survey Design Is Fatally Flawed

Keegan conducted an online survey comparing forehead thermometers. Keegan's Test condition asked respondents to compare purported photographs of a Medisim-manufactured and a K-Jump-manufactured thermometer, both in Rite Aid packaging, and indicate the

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[4] Keegan's "BestMed thermometer" is manufactured by K-Jump.

[5] Keegan was recently deemed unreliable. *Fail-Safe v. A.O. Smith Corp.,* 744 F.Supp.2d 870, 888 (E.D. Wis. 2010) ("[U]pon examination of each of the expert reports submitted by Dr. Keegan and his deposition testimony, the court concludes Dr. Keegan's proposed testimony not only falls on the unreliable side of the 'line,' but is all but domiciled there.").

manufacturing relationship between the devices. The Control condition asked respondents to compare supposed photos of the Medisim-manufactured thermometer, and a third-party thermometer, both in Rite Aid packaging, and indicate the manufacturing relationship between the devices. As discussed below, this Survey is riddled with egregious examples of flawed methodology, thus rendering it unreliable.

1. Keegan's Survey Does Not Accurately Replicate Market Conditions

"[A] survey must use the proper stimulus, one that tests for confusion by replicating marketplace conditions." *Conopco, Inc. v. Cosmair, Inc.*, 49 F.Supp.2d 242, 253 (S.D.N.Y. 1999). Surveys that fail to accurately depict actual market conditions are routinely excluded. *See e.g., Thoip v. The Walt Disney Co.*, 690 F.Supp.2d 218, 236-237 (S.D.N.Y. 2010)("... I conclude that the Ford Survey did not sufficiently approximate the manner in which consumers encountered the parties' products in the marketplace."). *Thoip v. The Walt Disney Co.*, 2011 WL 1792585 *6 (S.D.N.Y. May 10, 2011) ("[A] legally-probative estimation of consumer confusion must be tethered to marketplace conditions. . ."). *Louis Vuitton*, 525 F.Supp.2d at 581 ("A trademark survey must also approximate market conditions."); *Kargo Global, Inc. v. Advance Magazine Publishers*, 2007 WL 2258688 *7 (S.D.N.Y. 2007)("A survey's failure to approximate marketplace conditions can provide grounds for the survey's exclusion."). Keegan eschews replicating actual market conditions for a completely nonrepresentative marketplace, thus, his survey and opinions based thereon should be stricken.

Keegan's market conditions are fiction. The K-Jump manufactured thermometers and the Medisim manufactured thermometers, both in Rite-Aid packaging, were not sold during the same time period. BestMed was the distributor for both thermometers. BestMed, however, only

distributed the K-Jump version to Rite Aid after discontinuing the Medisim version.[6] Accordingly, the Medisim-manufactured thermometer in Rite-Aid packaging and the K-Jump-manufactured thermometer in Rite-Aid packaging do not exist together in the marketplace. Despite this, Keegan simulates a bogus market where the two products are sold side-by-side. This failure to even approach replicating actual market conditions renders Keegan's opinions worthless.

Making matters worse, Keegan fails to compare the actual current BestMed product with the actual current Medisim product.[7] Keegan could have compared the current BestMed and Medisim products, but did not. The apparent reason is that the existing Medisim-manufactured thermometer has a wholly dissimilar look from the outdated Medisim-manufactured thermometer including numerous significantly different characteristics relied upon in Keegan's Test and Control conditions. Maronick Decl. ¶5-10. Given these differences, had Keegan used the existing Medisim-manufactured thermometer, it is unlikely to have produced the reported high confusion rate among users, but not purchasers. Id. Keegan's fabrication of non-existing market conditions is particularly egregious since an accurate marketplace could have been used. *Louis Vuitton*, 525 F. Supp. 2d at 595 ("The error in methodology is especially troubling because, as stated above, Dr. Ericksen had prepared but did not show respondents a video in which the . . . lettering could have been seen."). It is clear that "such improper stimulus renders the survey so fundamentally unreliable that the flaw is enough on its own to justify exclusion under Rules 702 and 403." *Id.*

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[6] Indeed, Keegan acknowledges that ". . . Rite Aid does not currently offer for sale another Rite Aid branded digital temple thermometer other than the defendant's product . . ." Keegan Expert Report, page 3, fn. 2.

[7] Keegan notes that "[c]urrently, Walgreen's and Wal-Mart carry the plaintiff's product . . ." Keegan Expert Report, page 3, fn. 3.

2. Keegan's Survey Lacked a Proper Control and Thus is Unreliable

"A control is designed to estimate the degree of background "noise" or "error" in the survey. Without a proper control, there is no benchmark for determining whether a likelihood of confusion estimate is significant or merely reflects flaws in the survey methodology." *Thoip*, 690 F.Supp.2d at 240. To fulfill its function, a control should "share as many characteristics with the experimental stimulus as possible, with the key exception of the characteristic whose influence is being assessed." Ex. 11 at 258.

Keegan's control, a photograph of an Exergen thermometer that was digitally altered to appear in Rite Aid packaging, does not exist in the marketplace and shares few similarities with either the K-Jump-manufactured or the outdated Medisim-manufactured thermometers. As detailed in Dr. Maronick's Declaration, not only did size, shape, and look of the control thermometer differ, but the language of origin, description of the technology, and images on the packaging differed significantly. Maronick Decl. ¶11-14. It is, therefore, unsurprising that fewer respondents were able to "match" the control thermometer with the Medisim thermometer, which improperly inflated the results. In *Louis Vuitton*, this Court excluded a survey that used a control that was too different from the products at issue to operate effectively, like Keegan's control. *Louis Vuitton* at 525 F.Supp. 2d at 595-596 (rejecting survey where expert chose as his control a bag that was dissimilar in shape and pattern to the bags tested); see also *Conopco* (survey rejected where expert failed to use a control bottle that resembled the ETERNITY bottle). Keegan's control is similarly flawed. Thus, his Survey should be excluded.

Given these significant differences, Keegan's consumer confusion conclusion is without merit. The difference he asserts as reflecting consumer confusion is clearly due to the differences in the stimuli in the Test and Control conditions. Maronick Decl. ¶15. In failing to provide an adequate control, Keegan violates this basic principle of survey research.

Moreover, Keegan fails to indicate which feature of the outdated Medisim-manufactured product packaging is even being assessed. In the *Reference Manual on Scientific Evidence*, 2d Ed., Federal Judicial Center (2000), professor Diamond explains that the control stimulus should not share with "the experimental stimulus the feature whose impact is being assessed." Ex. 11 at 258. Yet, Keegan delineates no contours or limits of what he is testing. Accordingly, there is no indication from where the purported confusion stems, thus rendering his analysis meaningless.

3. Keegan's Survey Selects an Improper Universe

Identification of the proper universe for a survey "is a crucial step . . . [because] if the wrong persons are asked, the results are likely to be irrelevant." McCarthy on Trademarks 32:159, at 32-294. Keegan fails in selecting a proper universe of respondents.

When addressing the issue of confusion as to source "the only 'relevant population' is potential purchasers...." *Hutchinson v. Essence Comm., Inc.*, 769 F.Supp. 541, 546 (S.D.N.Y. 1991); see also, *Estee Lauder Inc. v. The Gap, Inc.*, 108 F.3d 1503, 1510 (2d Cir.1997) (a likelihood of confusion analysis requires proof that "'numerous ordinar[il]y prudent purchasers are likely to be misled or confused as to the source of the product in question because of the entrance in the marketplace of defendant's mark.'" (citations omitted). Keegan's survey fails in this regard.

Keegan did not survey purchasers or potential purchasers; and instead, surveys users of electronic thermometers. Ex. 10, Screener 2. A mere user of the product is not a potential purchaser of a product. *See, e.g. Universal City Studios, Inc. v. Nintendo Co., Ltd.*, 746 F. 2d 112, 118 (2d Cir. 1984)(". . . the survey utilized an improper universe in that it was conducted among individuals who had already purchased or leased Donkey Kong machines rather than those who were contemplating a purchase or lease."). *American Footwear Corp. v. General Footwear Co. Ltd.*, 609 F.2d 655, 661 n.4 (2d Cir.1979) (universe improper because although

survey participants may have once purchased hiking boots, it does not follow that they were presently interested in purchasing hiking boots). Respondents who are not potential consumers "may well be less likely to be aware of and to make relevant distinctions when reading ads than those who are potential consumers. The ability to make relevant distinctions is crucial when what is being tested is likelihood of confusion." *Weight Watchers Intern., Inc. v. Stouffer Corp.*, 744 F.Supp. 1259, 1273 (S.D.N.Y. 1990). "The definition of the relevant population is crucial because there may be systematic differences in the responses of members of the population and nonmembers. (For example, consumers who are prospective purchasers may know more about the product category than consumers who are not considering making a purchase.)" Ex. 11, p. 240. Users may never have purchased or considered purchasing the product, and instead some other household member may have been responsible for purchasing. By including only users, Keegan relies on "those whose perceptions are not relevant, thus skewing the results by introducing irrelevant data." McCarthy at 32.160 at 32-298-299.

The flaws in Keegan's Universe do not end there. Unlike in *Universal* or *American Footwear* where the Court concluded the universe to be improper because a previous purchaser was not necessarily a potential purchaser, Keegan provides no evidence that the thermometer user was ever a purchaser. Such an extreme violation of even the most basic tenet of survey research renders Keegan's survey, as well as the supposed confusion rate obtained from Keegan's deficient Survey, to be unreliable.

Keegan's Universe suffers from the addition problem that the majority of his respondents do not shop at Rite-Aid. Keegan's Survey purports to compare actual confusion associated with Rite Aid brand packaging, but fails to choose respondents who shop at Rite Aid. Ex. 10, (Keegan Rept. Ex. 6). Keegan's error is particularly egregious in view of the fact that his stimuli are thermometers in branded in Rite Aid packaging. Consequently, many respondents are answering

questions about a product sold at a retailer they do not patronize. This flaw, compounded by a respondent universe of non-potential purchasers, also renders Keegan's Survey unreliable.

B. Keegan's Survey Creates an Improper Bias

Surveys must control for pre-existing beliefs and misconceptions. *Procter & Gamble Co. v. Ultreo, Inc.*, 574. F.Supp.2d 339, 351 (S.D.N.Y. 2008)(citing *Pharmacia Corp. v. Glaxosmithkline Consumer Heatlhcare, L.P.*, 292 F.Supp.2d 594, 601 (D.N.J. 2003)) ("Controls are an essential feature of reliable survey evidence because they enable the surveyor to separate the wheat (the effect of the advertisement, alone, on the participant) from the chaff (the effect of the participant's prior knowledge and/or prior (mis)conceptions)."). Keegan's Survey fails to control for pre-existing beliefs, and affirmatively propagates what he is trying to prove namely the existence of a relationship between Rite Aid and the forehead thermometer manufacturer.

Keegan improperly influences his results by first suggesting that there is often a relationship between a retail store and its source manufacturers. "Survey questions should not be slanted or leading. Some commentators and courts have indicated that it is improperly leading to imply there could be a business relationship where the respondent may previously have not thought of any such connection." McCarthy (32:172). The Keegan introduction improperly taints the perceptions of the respondents by stating that there is commonly a relationship between Rite Aid branded products and the manufacturer:

> "Retail store chains commonly sell their own store branded products. Retail stores sometimes purchase such products from source manufacturers and sell them in the retail chain's store branded packaging." Ex. 10, (Keegan Rept. Ex. 5, p. 4).

Respondents are then asked to answer the survey questions with Keegan's statement in mind regarding the relationship between retail stores and manufacturers. As such, any purported confusion rate is skewed by the bias introduced into the Survey by Keegan.

Keegan's attempt to bias the Survey is exacerbated by his failure to do anything to control

pre-existing beliefs (or his self-created belief) that respondents may have regarding whether products with the Rite Aid brand are manufactured by Rite Aid or that there is some affiliation, connection, or association between Rite Aid and the manufacturers of the products. Oftentimes, the "difficulty is that the consumer's response to any question on the survey may be the result of information or misinformation from sources other than the trademark the respondent is being shown or the commercial he or she has just watched." Ex. 11, p. 256. By initially tainting the minds of the respondents and then failing to remedy the created bias, Keegan's findings simply fail to account for the effect of the respondent's belief that Rite Aid thermometer manufacturers are the same or share some relationship on his results.

Indeed, the significant impact of such a pre-existing belief is manifested in the fact that 38% of respondents believed the Medisim-manufactured and third-party thermometers Exergen were manufactured by the same manufacturer despite the significant differences between them. This inflated confusion rate can most likely be attributed to the Rite Aid brand located on all the packages and reflective of the pre-existing beliefs about products sold in Rite Aid stores. Maronick Decl. ¶ 16. For this reason as well, Keegan's survey, as well as all opinions based thereon, should be excluded under *Daubert* and Rules 702 and 403, Fed.R.Evid.

V. Conclusion

For the reasons discussed, BestMed respectfully requests that subject portions of Medisim's experts' technical and survey expert be stricken, and said experts precluded from offering any testimony thereon.

Respectfully submitted,

Dated: November 23, 2011

By: /s/ Joseph M. Kuo

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 23, 2011, a copy of the foregoing **BESTMED, LLC'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO STRIKE PORTIONS OF PLAINTIFF'S EXPERTS, LIPSON AND KEEGAN** was electronically filed with the Court via ECF which thereby served an e-mail notice upon the attorneys listed below:

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